

1 CLAIMS

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3 What is claimed is:

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5 Claim 1. A method for diagnosing or monitoring
6 multiple sclerosis (MS) in a mammal comprising:

7 obtaining a sample of body fluid from said mammal, wherein
8 said body fluid includes blood, blood products and saliva;

9 contacting said sample with at least one protein
10 associated with multiple sclerosis, wherein said contacting is
11 by an enzyme-linked immunosorbent assay (ELISA);

12 determining a level of at least one autoantibody specific
13 for said at least one protein in said sample; and,

14 comparing said level of said at least one autoantibody
15 with statistically significant levels thereof, wherein
16 diagnosis or monitoring of MS in said mammal is achieved.

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18 Claim 2. The method of claim 1, wherein said mammal is a
19 human.

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21 Claim 3. The method of claim 1, wherein said protein is myelin
22 basic protein (MBP).

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24 Claim 4. The method of claim 1, wherein said ELISA comprises
25 the steps of:

1 mixing said sample with at least one compound effective to
2 optimize the signal to noise ratio;

3 contacting said sample with an immunosorbent comprising
4 said at least one protein having a high specific affinity for
5 said at least one autoantibody; and,

6 determining an amount of said at least one autoantibody
7 bound by said at least one protein on said immunosorbent using
8 an antibody composition having an affinity for said at least
9 one autoantibody and operably linked to a signal generating
10 system.

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12 Claim 5. The method as in claim 4, wherein said signal
13 generating system is a tetramethylbenzidine substrate.

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15 Claim 6. The method as in claim 4, wherein said at least one
16 autoantibody is anti-MBP IgG.

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18 Claim 7. The method as in claim 6, wherein said antibody
19 composition comprises purified anti-human IgG conjugated to
20 horseradish peroxidase.

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22 Claim 8. The method as in claim 4, wherein said at least one
23 autoantibody is anti-MBP IgM.

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25 Claim 9. The method as in claim 8, wherein said antibody

1 composition comprises purified anti-human IgM conjugated to
2 horseradish peroxidase.

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4 Claim 10. The method as in claim **4**, wherein said at least one
5 autoantibody includes anti-MBP IgG and anti-MBP IgM.

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7 Claim 11. A kit for diagnosing multiple sclerosis (MS) or
8 monitoring disease state in MS patients, comprising:

9 at least one biomolecule or an immunologically detectable
10 fragment thereof which is upregulated in MS patients, said
11 biomolecule having an affinity for at least one additional
12 biomolecule whose presence is diagnostic of MS, said at least
13 one biomolecule being immobilizable on a solid support; and,

14 at least one labeled biomolecule having a binding affinity
15 for said at least one additional biomolecule;

16 whereby performance of at least one analysis determinative
17 of the presence of statistically significant levels of said at
18 least one biomolecule or an immunologically detectable fragment
19 thereof, is carried out on a sample of body fluid and provides
20 a means for diagnosing or monitoring disease state.

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22 Claim 12. The kit as defined in claim **11**, wherein said sample
23 of body fluid is blood, blood products, or saliva.

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25 Claim 13. The kit as defined in claim **11**, wherein said at

1 least one biomolecule is myelin basic protein (MBP).

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3 Claim 14. The kit of claim **11**, wherein said at least one
4 additional biomolecule includes anti-MBP IgM and anti-MBP IgG.

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6 Claim 15. The kit as defined in claim **11**, wherein said at
7 least one additional biomolecule is anti-MBP IgM.

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9 Claim 16. The kit as defined in claim **15**, wherein said labeled
10 biomolecule is anti-human IgM conjugated to horseradish
11 peroxidase.

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13 Claim 17. The kit as defined in claim **11**, wherein said at
14 least one additional biomolecule is anti-MBP IgG.

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16 Claim 18. The kit as defined in claim **17**, wherein said labeled
17 biomolecule is anti-human IgG conjugated to horseradish
18 peroxidase.

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20 Claim 19. The kit of claim **11**, wherein said monitoring is
21 carried out on a single sample.

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23 Claim 20. The kit of claim **11**, wherein said monitoring is
24 carried out on multiple samples such that at least one analysis
25 is carried out on a first sample and at least another analysis

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1 is carried out on a second sample.

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3 Claim 21. The kit of claim **20**, wherein said first and second
4 samples are obtained at different time periods.

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